

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING,
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION,

MDL No. 2419
Docket No. 1:13-md-2419-RWZ

THIS DOCUMENT RELATES TO:

Ziegler, et al. v. Ameridose, LLC, et al.
Civil Action Number 1:13-cv-12588-RWZ

CASE-SPECIFIC EXPERT REPORT OF MATTHEW C. LEE, M.D. R.Ph., M.S.

REPORT OPINIONS OF MATTHEW C. LEE, M.D., R.Ph., M.S.

QUALIFICATIONS

I am a practicing physician and pharmacist in Richmond, Virginia. I additionally have a Master's of Science in Pharmacology and Toxicology. I have presented my research findings both nationally and internationally as well as published the results in peer reviewed journals. My research was funded by the National Institute on Drug Abuse (NIDA).

In the course of my training and clinical practice as a physician and pharmacist, as well as through my research experience, I am familiar with the sterile compounding of medications, pharmacology of such medications, and risks and consequences administering adulterated medications.

I have worked as a pharmacist since 1995. My pharmacy experience entails work in retail compounding pharmacies, and hospital pharmacies where sterile compounding is routine. I have worked as a hospital pharmacist since 2008. I have been a question writer for the National Boards of Pharmacy Licensure Exam (NABPLEX) for the past three years. I am currently licensed to practice pharmacy in Virginia, North Carolina and Kentucky. I also currently own my own medical practice where I see adult patients with acute and chronic general medical conditions. I am licensed to practice medicine in Virginia.

I have been a Local Medical Examiner for the Commonwealth of Virginia since 2012. A Local Medical Examiner performs "views" on the bodies of person's who died outside of the hospital setting, when circumstances do not require internal autopsies. Such would be the case for suspected overdoses, where cause of death can be determined through toxicological analysis of body fluid samples.

I am familiar with the recognized standards of acceptable professional practice in the general medicine, pharmacy, pharmacology and toxicology in Nashville, Tennessee and similar communities. I am familiar with the availability of services in Nashville and similar communities in 2012.

In this report I will offer a summary of testimony and opinions that I may offer at trial in this case. All of my opinions will be offered to a reasonable degree of medical certainty within the field general medicine, pharmacy, pharmacology and toxicology.

INFORMATION REVIEWED AND EVENTS

During 2012, the Saint Thomas Outpatient Neurosurgical Center purchased the corticosteroid, methylprednisolone acetate (MPA), from New England Compounding Center (NECC).

I have reviewed the medical and billing records concerning the care and treatment of Mr. Adam Ziegler including injections of methylprednisolone acetate (MPA) at St. Thomas Outpatient Neurosurgical Center on September 11th, 2012, his subsequent treatment for fungal

scaroiliitis, osteomyelitis and myositis beginning in October of 2012, and further complications from therapy. I have reviewed the depositions of John Culclasure, M.D. and Debra Schamberg R.N. It is my understanding that Mr. Ziegler was injected with adulterated MPA compounded by the New England Compounding Center in Boston, Massachusetts. I have reviewed information regarding the compounding practices of NECC. I have also reviewed information, in the form of discovery responses filed by St. Thomas Outpatient Neurosurgical Center and Saint Thomas Hospital, regarding their purchasing practices for compounded medications.

Mr. Adam Ziegler was a 32 year old, six-foot six-inch, 260 pound male at the time he was administered adulterated MPA at St. Thomas Outpatient Neurosurgical Center on September 11th, 2012. Mr. Ziegler reported worsening pain in his left hip and buttock on September 20th, 2012. On October 4th, 2012 he was initially diagnosed with left scaroiliitis and a psoas abscess based on MRI findings. A follow up MRI on October 7th, 2012 showed progression of the abscess despite being on intravenous antibiotic therapy. Mr. Ziegler was subsequently diagnosed with fungal scaroiliitis, osteomyelitis and myositis. He was placed on antifungal medications with gradual improvement, requiring almost two years of medication therapy despite developing adverse reactions to the prescribed treatments.

It is my opinion that St. Thomas Outpatient Neurosurgical Center, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, Howell Allen Clinic, John Culclasure, M.D. and Debra Schamberg, R.N. failed to act with ordinary and reasonable care in accordance with the standard of care in Nashville, Tennessee, in the purchase of bulk, non-patient-specific, high-risk sterile injectable medications from the New England Compounding Pharmacy in June, July and August of 2012.

Further, it is my opinion that the negligence of St. Thomas Outpatient Neurosurgical Center, Saint Thomas West Hospital, Saint Thomas Network, Saint Thomas Health, Howell Allen Clinic, John Culclasure, M.D., and Debra Schamberg, R.N. caused Adam Ziegler to suffer injuries that he would not otherwise have suffered.

I reserve the right to amend this report in the event I am provided any additional materials or relevant information.

PREVIOUS TESTIMONY

I have attached to this report a list of cases that I have testified in by deposition or trial during the prior four years.

COMPENSATION

I am being compensated at a rate of \$500 per hour for working on this case.

Respectfully,


Matthew C. Lee, MD, RPh, MS
PHYSICIAN, PHARMACIST, PHARMACOLOGIST & TOXICOLOGIST

1/26/2016

CURRICULUM VITAE



MATTHEW C. LEE, MD, RPh, MS

PHYSICIAN, PHARMACIST, PHARMACOLOGIST & TOXICOLOGIST

5700 Old Richmond Avenue

Suite A-5

Richmond, VA 23226

Contact: 804.358.1492 Fax: 804.358.1491

eMail: mlee@eLEETePhysicians.com

I. EMPLOYMENT

eLEETe PHYSICIANS, LLC

Physician. eLEETe Physicians, LLC, Primary Care Practice. Primary care physician (PCP). Primary Care medical practice, diagnose and treat general medical conditions of adult patients 18 years old and over. Since 2008.



Pharmacist. Parallon Solutions. Provide patient care activities to ensure safe and effective drug therapy. Accurately enter orders in the computer and timely manner. Screen for drug interactions, allergies, or duplications, appropriate diagnosis, renal and liver function prior to order entry. Investigate and report adverse drug events and medication incidents. Review and interpret all physician orders received using patient profiles. Monitor for incompatibilities, concentration and rate of intravenous drugs. Assess orders for age specific appropriateness from neonatal through geriatric. Dissemination of drug information. Since 2008.



Medical Examiner for the Central District of the Office of the Chief Medical Examiner for the jurisdictions of Chesterfield, Hanover and Henrico counties and Richmond city. Appointed by the Chief Medical Examiner. Since 2012.



Veterans Evaluation Services Provider. Perform Forensic Legal Examinations of U.S. Military Veterans evaluating and assessing the extent of functional limitations or impairment related to a claimed condition. Since 2014.

II. WORK HISTORY:



Physician. Apple Mobile Medical. Occupational Health Physician at Teva Pharmaceuticals. Perform annual Employee Health Surveillance and pulmonary assessments on employees required to wear respirators. One to two weeks per year. (2011-2012)



Physician. United States Department of Defense, Military Entrance Processing Station (MEPS), Fort Lee Virginia. Physician, perform physicals on new military recruits to determine medical qualification as required for entrance into any branch of the U.S. Military as defined by the protocols established the U.S. Department of Defense. (2/2009 – 5/2012)



Physician. Apple Mobile Medical Occupational Health. Perform Personal Health Assessments on Pre- and Post- deployment soldiers in the United States National Guard. (9/2009 – 1/2011)



Physician. Locum Tenens in Occupational Health and Family Practice for Jackson and Coker. (2006 – 2007)

Zelda West Johnson, MD and Associates Family Practice- Physician in Family Practice. (2007 – 2008)

Pharmacist, Walnut Hill Pharmacy, Petersburg, VA (1995 – 2010)

Pharmacist; Poplar Springs Hospital; Petersburg, VA. (1995 – 2010)

Pharmacist for Wal-Mart pharmacy, as needed throughout Virginia (2000 – 2008)

Pharmacy Manager; Wal-Mart Pharmacy; Tarboro, NC. (1999 – 2000)

Lab Technician; Medical College of Virginia, Department of Pharmacology; Richmond, VA. (1999 – 2000)

Pharmacist; Prince George Pharmacy; Prince George, VA. (1995 – 2000)

III. EDUCATION AND TRAINING



Undergraduate - Barton College (previously Atlantic Christian College). September 1988 – May 1990.



Undergraduate - Virginia Commonwealth University, **Bachelor's of Science in Chemistry**. August 1992.



Professional - Medical College of Virginia, School of Pharmacy, **Bachelor's of Science in Pharmacy (B.Pharm)**. May 1995.



Graduate - Virginia Commonwealth University Department of Pharmacology/Toxicology. **Master's of Science in Pharmacology and Toxicology.** September 1997 – August 1999.
Thesis: The Role of several kinases in mice tolerant to delta-9 Tetrahydrocannabinol.



Doctoral - Virginia Commonwealth University School of Medicine, **Doctor of Medicine (M.D.).** May 2004.



Post-Doctoral - Internship in Internal Medicine, Virginia Commonwealth University Medical Center. July 2004 – June 2005.

IV. CERTIFICATIONS AND LICENSURE



Musculoskeletal Exam and Treatment Techniques, American College of Occupational and Environmental Medicine.



Medical Review Officer, Certified by the Medical Review Officers Certification Council.



Commonwealth of Virginia, license to practice medicine and surgery, since 2005



Commonwealth of Virginia, license to practice pharmacy, since 1995



State of North Carolina license to practice pharmacy, since 1999



Commonwealth of Kentucky license to practice pharmacy, since 2013

V. APPOINTMENTS



American College of Clinical Pharmacy Self-Assessment Program



Practice Update Primary Care Expert Editorial Board. Scan premier primary care journals. Summarize the most important, practice-relevant findings. Comment on these findings to help put them into perspective.



Medical Examiner for the Central District of the Office of the Chief Medical Examiner for the jurisdictions of Chesterfield, Hanover and Henrico counties and Richmond city. Appointed by the Chief Medical Examiner in 2012.



National Association of Boards of Pharmacy Licensure Exam (NAPLEX) question writer.



National Association of Boards of Pharmacy Standard Setting Committee.



National Association of Boards of Pharmacy Pharmacist
Assessment for Remediation Evaluation (PARE) item writer. PARE is a multi-dimensional assessment that the boards of pharmacy may use as an auxiliary tool when making decisions regarding pharmacist practice deficiencies that are due to noncompliance with pharmacy practice standards, laws or regulations, and result in compromises to patient safety.



National Academy of Sciences, Science & Entertainment Exchange Consultant.



CBS *Criminal Minds.*



Journal of Clinical Pharmacology Peer Review Board.



DynaMed Editorial Team Reviewer.
<http://www.ebscohost.com/dynamed>.

VI. PUBLICATIONS AND RESEARCH PRESENTATIONS



Proposed Mandatory Guidelines for Oral Fluid Testing in the Federal Workplace Drug Testing Programs. MRO Section Reviewer.



Proposed Revised Mandatory Guidelines for Urine Testing in the Federal Workplace Drug Testing Programs. (Adding the synthetic opioids, hydrocodone and oxycodone to the required testing panel). MRO Section Reviewer.



Medical Marijuana in the Workplace. A White Paper Prepared by the ACOEM Pharma and MRO Sections. ACOEM Position Paper on Medical Marijuana. Reviewer/editor.



ACOEM Medical Review Officer Review committee for the proposed rule to establish FMCSA Clearinghouse for drug and alcohol test results.



Two Cases of Alleged Dilaudid® Overdose: Sometimes it is, sometimes it is not. **Matthew C. Lee, MD, RPh, MS.** June 2013. www.HGExperts.com, www.JurisPro.com, www.ExpertPages.com.



DynaMed Editorial Team. Lee, M (Reviewer). Neuroleptic Malignant Syndrome. Last updated 2012 05 01. Available from *DynaMed*: <http://www.ebscohost.com/dynamed>.



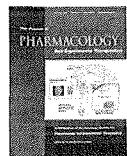
DynaMed Editorial Team. Lee, M (Reviewer). Paralytic Shellfish Poisoning. Last updated 2012 06 21. Available from *DynaMed*: <http://www.ebscohost.com/dynamed>.



DynaMed Editorial Team. Lee, M (Reviewer). Anti-Cholinergic Poisoning. Last updated 2012 11 27. Available from *DynaMed*: <http://www.ebscohost.com/dynamed>.



Assessment of Marijuana Intoxication. **Matthew C. Lee, MD, RPh, MS.** October 4th, 2010. www.HGExperts.com, and www.ExpertPages.com. Quantum Free Will. **Matthew Lee.** *New Scientist*. September 1st-7th, 2007; 195(2619):25. <http://www.newscientist.com/article/mg19526195.100-quantum-free-will.html>



The Role of Several Kinases in Mice Tolerant to Delta-9 Tetrahydrocannabinol. **M. Lee, D. Stevens, S. Welch.** *Journal of Pharmacology and Experimental Therapeutics*. 2003 May; 305(2):593-9. <http://jpet.aspetjournals.org/content/305/2/593.full.pdf+html>

The Effects of Blocking Several Kinases in Mice Tolerant to Δ9-THC.

Matthew C. Lee, David L. Stevens and Sandra P. Welch. Virginia Academy of Sciences May 1999.



Reversing Δ9-THC Antinociceptive Tolerance by Inhibiting the Phosphorylation of the CB1 Receptor. **Matthew C. Lee**, David L. Stevens and Sandra P. Welch. FASEB, 1999.



The Role of Several Kinases in Mice Tolerant to Δ9-THC. **Matthew C. Lee**, David L. Stevens and Sandra P. Welch. International Cannabinoid Research Society, 1999.

VII. HONORS AND AWARDS



Distinguished Service Award. Virginia Commonwealth University.



University Leadership Award. Virginia Commonwealth University.



Local Association President's Award. Virginia Pharmacist's Association.



Professionalism Award. American Pharmaceutical Association/McNeil Consumer Products.



Allen and Hanbury's Pride in Pharmacy Scholarship Award.

VIII. VOLUNTEER ACTIVITIES

Physician Volunteer, Fan Free Clinic, Richmond, VA.

Foundations of Clinical Medicine Assistant Instructor.

Professionalism Workshop Group Leader.

Virginia Pharmacist's Association Board of Directors.

Speaker's Bureau for the Pitt County (North Carolina) AIDS Service Organization (PICASO).

IX. PROFESSIONAL MEMBERSHIP

American College of Clinical Pharmacy



American College of Clinical Pharmacy



American College of and Occupational and Environmental Medicine



American College of Forensic Examiners Institute



American Medical Association



American Pharmacists Association



Medical Society of Virginia



American Society of Pharmacy Law

Richmond Academy of Medicine

Testimony Case Summary

December 17, 2015

	Law firm/Attorney	Date	Location	Plaintiff or Defense	Case	Outcome	Circumstances
1.	Arnold, Torado, and Welch. Columbus, OH Jerry Torado, Esq. 2075 MarbleCliff Office Park Columbus, OH 43215	3/12	Columbus, OH	D	Miller v Andrews	Settled (Deposed)	?HIT, DVT, subtherapeutic INR on Coumadin, Rx Lovenox. ?Whether Lovenox was contributing factor for worsening Lower Ext thrombus due to hx of HIT, and resulting amputation.
2.	Harris, Matthew & Crowder, PC. (CalSpencer, Esq.)	5/12	Lunenburg, VA	D	Commonwealth of Virginia v. Alan Cryderman	(Criminal) Testified at sentencing hearing.	Oxycodone-alcohol effects on body, mind and memory.
3.	Rapoport Law Office (Michael Teich, Esq.)	4/12	Chicago, IL	P	Martynowicz v. Walgreen's	Settled 9/13. Deposed 7/10/12	Misfill Synthroid, resulting in hypothyroid during 2 nd trimester of pregnancy, cognitive developmental issues.
4.	Snook & Haughey Charlottesville, VA Lloyd Snook, Esq. Lou Diamond, Esq.	1/9/13	Charlottesville, VA	D	USA v. Stephen McFadden (Federal)	(Criminal case) Jury Trial	"Bath Salts", Substantially similar, Analogs, Controlled Substance Act. Methylone, MDPV, 4-MEC.
5.	Rod Sager Law Offices Rod Sager, Esq. Richmond, VA	6/12	Richmond, VA	P	Martin v. Rubin	Deposed Settled December 2012	NSAIDS, Corticosteroids, Tobacco (Smoking), on wound healing, and non-union.
6.	Barnes and Cohen, PA (Glen E. Cohen, Esq.)	6/11	Chatam County, GA	P	Roosevelt Johnson, Jr. v. State of Georgia and Gateway Behavioral Health Services,	Deposed 9/12 Settled.	NMS secondary to Haldol decanoate injection, secondary UEDVT.
7.	Jordan, Coyne & Savits Deborah Wheilan, Esq. Fairfax, VA		Vienna, VA	D	Franco v. Metrocall	Deposed 3/13 Settled	Reasonableness of medications. Medication costs, projected costs.

	Law firm/Attorney	Date	Location	Plaintiff or Defense	Case	Outcome	Circumstances
8.	Gardner, Maupin, Sutton & Haney, P.C. Mark Gardner, Esq. The Professional Building PO Box 129 Spotsylvania C.H., VA22553	2/13	Stafford County, VA	D	Commonwealth of Virginia v. Karen E. Walls	(Criminal) Jury trial, February 14 th , 2013. Expert - Pharmacology and toxicology relative to medications and impairment. Medical doctor relative to SVT and Pain Management. Mistrial – Deadlocked jury. No retrial/Chgs dropped.	Expert in Internal Medicine, Cardiology, Pharmacology/Toxicology. SVT episode. Soma, oxy, diaz for chronic pain. Appeal of DUI conviction.
9.	Stallings, Bush & Randall, P.C. Sonny Stallings Va.Beach, Va.	9/24/13	Virginia Beach, VA	D	Comm. Of VA vs. Jocelyn Anderson.	(Criminal) Bench trial. DUI Charges dismissed. Involuntary Intoxication.	Accepted as pharm/tox expert, medical doctor, pharmacist, MRO. DUI – Involuntary intoxication. Diphenhydramine (hair sample) and etoh. Date rape drug.
10.	McEachin and Gee Donald McEachin, Esq. Priscilla Woody, Esq.	10/31/13	Richmond, VA	P	Sneden v. Do.	Jury trial (Civil) Personal Injury, auto accident. Def was drinking alcohol.	Accepted as Medical and Toxicology Expert.
11.	Klabugh Pfund & Messersmith EricAndrew, Esq.	3/2013	Roanoke, VA	D	Franklin v. Kmart, Lynchburg General Hospital	Deposed November 2013	ESRD, COPD, rec'd altace instead of pred. development of ischemic bowel.
12.	Pullin, Fowler, Flanagan, Brown & Poe PLLC Linsey Amores, Esq.	3/2014	Charleston, WV	D	Unik v. RxByTel	Deposed May 2014 (Settled)	Wrongful death secondary to fentanyl patch. Question of dose interpretation as written by MD, as well as causation.

	Law firm/Attorney	Date	Location	Plaintiff or Defense	Case	Outcome	Circumstances
13	Habush Habush & Rottier S.C. D. James Weis, Esq.	3/2014	Wausau, WI	P	Buettner v. Aspirus Wausau Hospital	Deposed July 2014 Settled December 2014	Inadvertent administration of epinephrine IV vs. subq or IM as indicated. Causation.
14	Shapiro, Lewis Appleton & Duffan P.C. James Lewis, Esq. Virginia Beach, VA	10/2014	Rockville, NC	P	Alsup v. Carolinas Medical Center/ Cabarrus ER Assoc.	Deposed 11/4/2014	Fentanyl patch overdose. Narcan via EMS. New patch applied in ER, dc'd after 4 hours. Found dead next day. Cause of death Fentanyl OD.
15	Albo & Oblon, LLP Dave Albo Springfield, VA	11/6/14	Fairfax, VA	D	Comm of Va vs. Cruz.	(Criminal) Trial 11/6/2014 Null Processed	THC metabolite, (THC-COOH) basis for DUI.
16	Stallings, Bush & Randall, P.C. Sonny Stallings Va Beach, Va.	4/10/14	Virginia Beach, VA	D	Comm. Of VA vs. Angela Abby	(Criminal) Bench trial 4/10/14. Charges dismissed	DUI – Involuntary intoxication. Diphenhydramine (hair sample) and etoh. Date rape drug.
17	Frost Brown Todd LLC Anthony Overholt, Esq. Indianapolis, IN	7/2014	Indianapolis, IN	D	Flannery Estate v. City of Indianapolis	Deposed 10/20/2014 Settled	Death in custody, post-mortem tox: etoh, synthetic cannabinoids.
18	Spence Law Firm Regina Guy, Esq. Memphis, TN	6/2014	Memphis, TN	P	Mayfield v Methodist University Hosp, Memphis	Deposed 11/11/2014	Perc/Dilau/Xanax Resp failure in pt with IPF/SLE who devel pneu.
19	Cantor, Stoneburner, Ford Grana & Buckner. Bellamy Stoneburner, Esq. Richmond, VA	11/13	Richmond, VA	P	Fountain v MEDERVA	Deposed 1/20/2015 Settled	Ropivacaine overdose, caudal epidural, 21 month old, premie, FTT.
20	Patrick, Beard, Schulman & Jacoway, P.C. Michael Anderson, Esq. Chattanooga, TN	1/14	Rhea, TN	P	Ballard v. ECC	Deposed 2/9/2015	Peds SJS, Septra, MRSA prophylaxis.

	Law firm/Attorney	Date	Location	Plaintiff or Defense	Case	Outcome	Circumstances
21	Belsky, Weinberg & Horowitz, L.L.C. Thomas Glancy, J., Esq. Baltimore, MD	1/14	Finksburg, MD	P	Karon Moore v. Rite Aid	Deposed 2/13/2015	Chloroquine for malaria prophylaxis dispensed with directions to take daily.
22	Hall and Sethi Gobind Sethi, Esq.	6/14	Reston, VA	P	Stirk v Wilson	Deposed 07/23/2015	Coumadin dosing error, subsequent stroke.
23	Prosecution Services Bureau State of Montana Mary Cochenour, Esq State Prosecutor Helena, Montana	9/15	Helena, MT	Prosecute	State of Montana v. Joseph Campbell	(Criminal) Testified at hearing 9/1/2015	Homicide, post-mortem tox with THC. Effects of THC.
24	The Law Office of John A. Blazer. John Blazer, Esq Fairfax, VA	3/14	Fairfax, VA	P	Steinhardt v. Giant Pharmacy	Deposed 9/25/2015	Pharmacy standard of care regarding prescription counseling, vaccinations and informed consent.
25	Marsh, Rickard & Bryan Roger Lucas, Esq. Birmingham, AL	8/15	Jefferson County, AL	P	Jones v. David's Discount Pharmacy	Deposed 10/20/2015	Rx misfill, methadone for methimazole. Methadone toxicity. Cause of death.
26	The Edwards Law Firm Mark Edwards, Esq.	12/12	Tulsa, OK	P	Persinger v Jaiswal Clinic, Lindsay Pruett, PA.	Deposed 11/3/2015	Coumadin – Bactrim interaction, lack of monitoring.
27	The Clifford Law Firm Keith Hebeisen, Esq. Chicago, IL	2/15	Chicago, IL	P	Vandelinder v Northwestern Memorial Hospital	Deposed 11/16/2015	Foscarnet overdose/toxicity, renal failure, pancytopenia, immunosuppression.
28	The Spence Law Firm Regina Guy, Esq. Memphis, TN	9/15	Memphis, TN	P	McGill v Methodist Hospital	Deposed 11/20/2015	Sumitriptan administration, indications, pharmacology, headache diagnosis